In the United States Court of Federal Claims

Case No. 08-788C
(Filed: June 11, 2009, UNDER SEAL)
Filed: August 17, 2009, REDACTED, PUBLIC VERSION*

* *

GENPHAR INC.,
Plaintiff,

v.

THE UNITED STATES OF AMERICA,
Defendant,

CRUCELL HOLLAND BV,
Intervenor,

and

INTEGRATED BIO THERAPEUTICS, INC.
Intervenor.

* *

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Daniel R. Forman, Crowell & Moring, LLP, attorney of record for the Intervenor, Integrated Bio Therapeutics, Inc. With him on the briefs were ***H. Bryan Brewer, III*** and ***Puja Satiani***.

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*See Court Order issued this date explaining redactions, which appear in brackets.

OPINION AND ORDER

BASKIR, Judge.

This is a post-award bid protest. Plaintiff, GenPhar, Inc. (GenPhar) unsuccessfully bid on a contract with the Defendant, National Institute of Allergy and Infectious Diseases (NIAID), to develop a vaccine to protect against various strains of the Ebola and Marburg virus. The contracts went to competing bidders, Crucell Holland BV (Crucell) and Integrated Biotherapeutics (IBT), which submitted proposals with higher technical marks at substantially lower costs. GenPhar now seeks injunctive relief to prevent NIAID from continuing to implement the awarded contracts. Plaintiff claims first, that the agency improperly excluded it from the competition, and second, that the agency committed various procurement violations, including improperly changing the solicitation's requirements and ignoring an illegal conflict of interest.

This matter is before us on the parties' respective Motions for Judgment on the Administrative Record. **For the following reasons, we GRANT Defendant's and Intervenors' respective Motions for Judgment on the Administrative Record and DISMISS GenPhar's protest.**

I. BACKGROUND

We recite the relevant facts taken from the Administrative Record (AR), the parties' briefs, and oral argument before this Court on March 25, 2009.

A. Solicitation

The filoviradae virus contains two genera, Ebola and Marburg. Broad Agency Announcement NIH-BARDA-NIAID-DMID-A12007003 (BAA), Attachment (Att.) 4. Outbreaks of Ebola and Marburg occur mostly in Africa and cause viral hemorrhagic fever in humans with a high mortality rate. *Id.* No licensed vaccines for filovirus protection exist, and treatment is limited to standard of care. *Id.* In part due to the high mortality rate, NIAID has identified filovirus vaccines to be priority biodefense products, and many attempts have been made to develop them. *Id.*

However, two major obstacles have prevented their successful development. First, while initial vaccines effectively protected small animal models from infection, success has been extremely limited in the more stringent non-human primate (NHP) challenge models. *Id.* NIAID believed the protection of NHP challenge models against filoviruses to be an important milestone as these models most closely resemble the human disease in terms of progression and pathogenesis. *Id.*

The second challenge is the emergence of multiple species and strains of Ebola and Marburg. BAA, Att. 4. Current vaccines are limited in their ability to cross-protect against multiple viral strains, therefore NIAID sought to develop a "multivalent" vaccine

using "platform technology." *Id.* A multivalent vaccine, as opposed to monovalent, immunizes against several diseases with one dose, aptly described by GenPhar as a "defense ballistic missile with multiple warheads capable of striking several incoming targets at once." Plaintiff's Complaint (Compl.), ¶ 7. The use of platform technology would allow the vaccine to be rapidly adapted into different products as new virus strains emerge. *Id*; Compl., ¶ 6, n. 1.

In light of these challenges, NIAID issued the instant solicitation on September 18, 2007. NIAID's objective was to develop a multivalent filovirus vaccine that would protect against both the Ebola and Marburg virus, ultimately to enable the government to stockpile these vaccines to protect the American public. BAA, Att. 4. The solicitation anticipated issuing two or three multi-year, cost reimbursement, completion type contracts. NIAID Source Selection; BAA, Att. 4. The awards would provide a base period of funding for five years beginning on or around September 20, 2008, and three discretionary options of an additional four years for a maximum period of performance of nine years. BAA, Att. 4. We identify the relevant technical requirements and evaluation scheme below.

1. Research and Technical Objectives

In line with the challenges stated above, the threshold requirements for candidate vaccines were two-fold: the use of a platform technology, and demonstrated success in non-human primate Ebola and Marburg models. BAA, Att. 4.

Offerors meeting these initial requirements were asked to prepare a technical proposal, setting forth product development and implementation plans for their candidate vaccines. *See id.* The solicitation identified numerous technical requirements for the base and option periods, in particular, a Phase I Clinical Trial to be conducted by the awardees during the base period. *Id.*

In addition to the technical proposal, the solicitation required that offerors submit a Statement of Work (SOW), setting forth all activities and proposed timelines to be performed by the awardees. BAA, Att. 6, Sec. 3. The SOWs were to acknowledge the agency's right to modify the "milestones, progress, schedule, budget, or product to add or delete products, process or schedule" as needed. *Id.* The SOWs proposed by the offerors were to be negotiated and accepted by NIAID and ultimately incorporated into the final contracts. *Id.*

2. Evaluation Scheme

NIAID made clear this solicitation was not a conventional request for proposal (RFP). Contrary to the standard RFP, proposals here would not be evaluated against a specific government need. BAA, Att. 3. Given the uncertainty in candidate vaccine efficacy, the program was to be an iterative process. *Id.* The candidate vaccines would require ongoing evaluation as to their potential for success in meeting the desired

vaccination and stability objectives. BAA, Att. 4. NIAID reserved the right to make awards to "cover significantly different novel vaccine concepts as a mechanism to achieve programmic balance" and to the offerors whose proposals provided the "best overall value" to the government. RFP, 89.

As to technical scores, offerors could receive a maximum of 140 points under the base period and a maximum of 30 points under the options period, for a total possible score of 170 points. RFP, 93. NIAID's designated scientific review group, known as the "Special Emphasis Panel" (Panel), would evaluate the proposals against the following criteria, listed in descending order of importance:

1. Current product development status [45 points];
2. Technical plan/approach [40];
3. Scientific, technical, and management personnel [25];
4. Facilities, equipment, biocontainment safety, and training [15]; and
5. Project management [15].

RFP, 89-96. On the basis of the proposals' respective relevance and technical merit, the Panel would establish an Order of Merit Ranking in lieu of a competitive range. BAA, Att. 3. Based on this ranking, the Panel would then recommend offerors with whom NIAID would commence negotiations. *Id.* During this time, all aspects of the proposal would be subject to discussion, including cost, technical approach, and contractual terms and conditions. BAA, Att. 4. NIAID's final selection for contract award would be based on an evaluation of proposals against three factors, in order of importance: technical, cost, and small disadvantaged business participation. RFP, 89.

B. Offerors

Four bidders, GenPhar, Crucell, IBT, and BioProtection Systems (BioProtection) submitted timely proposals, summarized below. BioProtection has not intervened in this action.

1. GenPhar

Since its founding in 1999, GenPhar has collaborated with various Federal agencies to develop numerous multivalent vaccines, including one for the Ebola and Marburg virus. Pl.'s Technical Proposal (Tech. Pr.), 107. GenPhar's research has resulted in a number of domestic and international patents, most notably involving the use of the adenovirus vector. *Id.* at 192. An adenovirus is any virus of the family *Adenoviridae*, many of which are responsible for respiratory infections in humans. STEDMANS MEDICAL DICTIONARY 7370 (27th ed. 2000). The virus is conveyed by a vector, which serves as a vehicle to transport pathogens from one host to another. *See generally id.* at 432790.

Pursuant to the solicitation, GenPhar proposed a vaccine candidate that uses an adenovirus vector type 5 (Ad5). GenPhar claims its candidate is the only multivalent filovirus vaccine in the world that has demonstrated complete protection against repeat infections of five strains of Ebola and Marburg. Pl. Agency Protest, AR 6060.

2. Crucell

Crucell is a fully integrated biopharmaceutical company that develops, produces, and markets products to combat infectious diseases. Crucell's Original Business Proposal (Bus. P.). In 2002, Crucell began working on Ebola and Marburg vaccines in collaboration with the Vaccine Research Center (VRC) of the National Institutes of Health (NIH), a division of the NIAID. Crucell's Revised Tech. Pr., 17. Their collaboration was pursuant to a Cooperative Research and Development Agreement (CRADA) to jointly develop, test, and manufacture adenovirus-based vaccines. *Id.* Relying on "key scientific discoveries" developed by the Crucell-VRC collaboration, Crucell proposed a vaccine candidate that uses a [ ], a vector into which foreign DNA has been inserted, to deliver the Ebola and Marburg viruses. *Id.*; STEDMANS MEDICAL DICTIONARY 432790 (27th ed. 2000).

3. IBT

IBT was founded in 2005. It owns intellectual property in vaccines for several biodefense and emerging infectious disease agents, including exclusive licenses for various multivalent filovirus vaccines. IBT's Original Tech. Pr., 14-15. Pursuant to this solicitation, IBT proposed a multivalent filovirus vaccine capable of protecting against both the Ebola and Marburg virus. *Id.* at 9. The underlying technology is [ ] efficacious in both monovalent and multivalent settings in NHP models. *Id.*

C. Selection and Award

On March 20, 2008, the Panel convened to review and evaluate the four proposals. The Panel's nine members comprised scientists and medical doctors employed in the private sector. BAA Meeting Roster, AR 545-47. The chairperson was the Panel's sole government official, employed by the Food and Drug Administration. *Id.* Each evaluator completed an Individual Technical Evaluation Score Sheet and an Individual Technical Evaluation Summary for all four proposals. *See* Tab 5.

At the outset, the Panel identified NIAID's Independent Government Cost Estimate (IGCE) as $66,987,554. Panel's Order of Merit Ranking (Order of Merit), AR, Tab 10. The proposals' projected total costs from lowest to highest were as follows: Crucell, $46,306,740; BioProtection, $48,266,595; IBT, $59,420,984; and GenPhar, $214,949,619. *Id.* The Panel found all proposals technically acceptable and upon averaging of technical scores ranked the proposals from highest to lowest as follows: IBT, 141; Crucell, 138; BioProtection, 117; and GenPhar, 111. *Id.*

GenPhar received poor marks. In addition to its relatively high cost and low technical score, the Panel identified numerous production, regulatory and management concerns with GenPhar's proposal. Order of Merit, AR 957. The Panel concluded that no mechanism was apparent that could reduce GenPhar's costs "to a point where it would be considered affordable and technically viable." *Id.* The Panel advised NIAID that no further action be taken with GenPhar. *Id.* On or around July 24, 2008, GenPhar received notice that NIAID was no longer considering its proposal. NIAID's letter to GenPhar, AR 1013. Similarly, though BioProtection received the third highest technical score and submitted the second-lowest cost proposal, the Panel advised NIAID that no further action be taken on BioProtection's proposal. *See* Order of Merit.

The Panel provided positive reviews for the two offerors receiving the highest technical marks, IBT and Crucell, and recommended that NIAID open negotiations with them. *Id.* NIAID initiated negotiations with IBT and Crucell, during which it addressed concerns as to various issues arising from their proposals. *See e.g.* NIAID's letter to Crucell, AR 1010. IBT and Crucell modified their SOWs accordingly. This resulted in the shifting of various technical requirements, for example, from the base period to the option periods. The extent of these changes will be addressed later in our analysis. The negotiated decreases in various proposed costs allowed IBT to reduce its overall costs for the base period from $36,401,852 to $22,528,134, a change of $13,873,718. IBT Cost Analysis, AR 875. At the same time, these negotiations led to an increase in Crucell's proposed total cost for the base period from $21,196,620 to $29,819,597, a change of $8,622,977. Crucell's Cost Analysis, AR 830.

IBT and Crucell submitted to NIAID Final Proposal Revisions incorporating the negotiated changes. On September 24, 2008, NIAID concluded that Crucell and IBT's proposals offered the best value to the government. *See* Contracting Officer's Final Selection Decision, AR 962. It awarded cost-plus-fixed fee type contracts to Crucell and IBT for a total possible amount, including options, of $70,345,310 and $65,280,687, respectively. *Id.* The contracts incorporating the modified SOWs were fully executed on or around September 30, 2008. *See* Tabs 40, 41.

D. Agency Protest

On July 29, 2008, four days after being notified of its elimination, GenPhar attempted to contact NIAID. *See* Tab 40. In an email dated July 30, 2008, GenPhar expressed its disappointment and requested a copy of the Panel's comments to allow "changes to be made in our performance." *Id.* GenPhar advised it was entering "the death of valley [sic]" in terms of its product development and would not be able to continue without NIAID's support. *Id.* Apparently due to a lack of response, GenPhar renewed its request via email on August 1, 2008, and then by letter on August 12, 2008. *Id.*

NIAID responded on August 19, 2008, and, after some communication with GenPhar, agreed on August 26, 2008, to issue a debriefing as soon as it completed

negotiations on the solicitation. On September 25, 2008, one day following the award to IBT and Crucell, NIAID provided to GenPhar a written debriefing and a four-page summary of findings. *See* Panel's Debriefing, Tab 38. In it, NIAID reiterated the Panel's numerous production, regulatory and management concerns in GenPhar's proposal, as the following excerpts illustrate:

> [GenPhar] does not provide sufficient data indicating that [its proposal] is safer than traditional adenovirus vaccines.
> . . .
> [GenPhar] totally relies on [subcontractors] for critical GMP operations, and [GenPhar] does not have the in-house expertise to manage them.
> . . .
> All activities described for scale-up and optimization of cGMP manufacture at [subcontractor] will be duplicated [by Plaintiff] . . .. [t]his may not be an optimal use of resources.

Id.

On or around October 2, 2008, GenPhar received official notice of NIAID's award to IBT and Crucell. *Id.* Four days later on October 6, 2008, GenPhar filed an agency protest, claiming its vaccine to be "the most promising candidate" and the "only vaccine that has truly met or surpassed all the requirements outlined in the RFP." *Id.* Under the Federal Acquisition Regulation (FAR), protests are to be filed no later than ten days after the basis of protest is known or should have been known, whichever occurs earlier. 48 C.F.R. § 33.103(e). Finding the ten-day protest clock to have begun on September 25, 2008, when the debriefing was issued, NIAID deemed the protest untimely by one day. NIAID thereby dismissed the action. It apparently never formally responded to GenPhar's subsequent reconsideration requests.

E. Procedural History

GenPhar filed its Complaint in this Court on November 4, 2008. GenPhar's challenges fall into two broad categories. First, GenPhar was arbitrarily and capriciously excluded by Defendant from the competition. Second, NIAID improperly modified the solicitation requirements after GenPhar's elimination and violated conflict of interest provisions in awarding the contract to Crucell. On December 10, 2008, GenPhar filed a Motion for Judgment on the Administrative Record, seeking preliminary and permanent injunction for Defendant to terminate the contract awards to IBT and Crucell and reissue the BAA. Plaintiff's Reply, 8; Transcript of Oral Argument (Tr.) at 57, March 25, 2009.

Crucell and IBT filed motions to intervene, both of which were granted on November 6, 2008. They and Defendant filed respective cross-motions for judgment on the administrative record. Defendant seeks judgment on two grounds: first, the record demonstrates a coherent and reasonable explanation for NIAID's decision to exclude GenPhar from the competition; and second, NIAID committed no "clear nor prejudicial" procurement violations to warrant resolicitation. The matter is now before us on the

parties' respective motions for judgment on the administrative record.

II. DISCUSSION

A. Applicable Legal Standards

This court has jurisdiction to hear post-award bid protests pursuant to 28 U.S.C. § 1491(b)(4). At the outset, we find Plaintiff qualifies as an "interested party" and has standing to protest the procurement under 28 U.S.C. § 1491(b)(1).

The Federal Circuit has held that standing to bring a bid protest is "limited to actual or prospective bidders or offerors whose direct economic interest would be affected by the award of the contract or by failure to award the contract." *Am. Fed'n of Gov't Employees v. United States*, 258 F.3d 1294, 1302 (Fed. Cir. 2001). To demonstrate that it was an "interested" party, GenPhar must show that it would have "greater than an insubstantial chance of securing the contract if successful on the merits of the bid protest." *Info. Tech. & Applications Corp. v. United States (ITAC)*, 316 F.3d 1312, 1319 (Fed. Cir. 2003).

GenPhar claims that it was prejudiced when NIAID improperly evaluated and excluded its proposal from the competition, thereby depriving GenPhar of the opportunity to compete fairly for at least one of the three possible awards. Following its improper elimination, GenPhar claims NIAID illegally modified the solicitation without giving GenPhar an opportunity to amend its proposal in accordance with the changes. Compl., ¶ 83-87. Absent these alleged errors, GenPhar argues it would have had a "substantial chance" of receiving a contract award, at least as to the third contract contemplated by the BAA. Pl.'s Supplemental Brief (Supp. Br.), 3.

For standing purposes, we agree. This is not a case in which a contractor failed to submit or withdrew its proposal. *See e.g. MCI Telecomm. Corp. v. United States*, 878 F.2d 362 (Fed. Cir. 1989); *see also Fed. Data Corp. v. United States*, 911 F.2d 699 (Fed. Cir. 1990). If GenPhar's allegations were sustained, NIAID may be required to cancel the original solicitation and reissue the BAA. *See* 48 C.F.R. § 15.206(e). GenPhar is unquestionably a qualified bidder with a technically acceptable proposal. Given the opportunity to compete fairly, GenPhar would arguably have greater than an insubstantial chance of receiving a contract award, at least as to the third contract.

Standing having been satisfied, we review the agency's actions pursuant to the standards set forth in the Administrative Procedure Act (APA). 28 U.S.C. § 1491(b)(4). Pursuant to the APA, we accord the agency deference, only setting aside an action or decision that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Banknote Corp. of Am. v. United States*, 365 F.3d 1345, 1350 (Fed. Cir. 2004). Our analysis considers whether: (1) the procurement official's decision lacked a rational basis; or (2) the procurement involved a violation of regulation or procedure. *Impresa Construzioni Geom. Domenico Garufi v.*

United States, 238 F.3d 1324, 1332 (Fed. Cir. 2001).

When challenging the procurement as arbitrary and capricious, the plaintiff must do more than identify circumstances in which the procuring agency made a mistake; it must establish that such a mistake was so excessive as to fall outside the decision-maker's ambit of discretion. *See Banknote*, 365 F.3d at 1351. Absent such findings, the court is "highly deferential" to the agency's procurement decision. *Advanced Data Concepts, Inc. v. United States*, 216 F.3d 1054, 1058 (Fed. Cir. 2000). If the court finds a reasonable basis for the agency's action, it should "stay its hand even though it might, as an original proposition, have reached a different conclusion . . .". *Honeywell, Inc. v. United States*, 870 F.2d 644, 648 (Fed. Cir. 1989). Our deference to the agency decision is particularly great when the procurement is a "best value" procurement, as here. *TRW, Inc. v. Unisys Corp.*, 98 F.3d 1325, 1328 (Fed. Cir. 1996) (holding that where the court reviews technical matters within the agency's expertise, the highest degree of deference is warranted).

When challenging the procurement on the basis of a regulatory violation, the protestor "must show a clear and prejudicial violation of [the] applicable statutes and regulations." *Banknote*, 365 F.3d at 1351; *Advanced Data Concepts, Inc.*, 216 F.3d at 1057. To establish prejudice on this ground requires that the protestor show there was a "substantial chance" it would have been awarded the contract absent the alleged error. *Alfa Laval Separation, Inc. v. United States*, 175 F.3d 1365, 1367 (Fed. Cir. 1999). Prejudice thus enters the analysis of bid protest actions in two ways: first in analyzing whether the protestor has standing to pursue its claims, as discussed above, and then near the end of the analytical process in determining whether relief is warranted. *See Systems Plus, Inc. v. United States*, 69 Fed. Cl. 757, 769 (2006).

Should the protester prevail, the Court "may award any relief that [it] considers proper, including declaratory and injunctive relief except that monetary relief shall be limited to bid preparation and proposal costs." 28 U.S.C. § 1491(b)(2). In deciding whether a permanent injunction is warranted, a court considers: (1) whether the plaintiff has succeeded on the merits of the case; (2) whether the plaintiff will suffer irreparable harm if the court withholds injunctive relief; (3) whether the balance of hardships to the respective parties favors the grant of injunctive relief; and (4) whether it is in the public interest to grant injunctive relief. *Centech Group, Inc. v. United States*, 554 F.3d 1029, 1037 (Fed. Cir. 2009) (citations omitted).

B. "Competitive Range" Determination

We first scrutinize the record to determine whether NIAID's decisions to rank GenPhar fourth in the Order of Merit and ultimately eliminate Plaintiff from the competition were reasonable. The crux of Plaintiff's argument, it seems to us, is the alleged superiority of GenPhar's proposal relative to the awardees. GenPhar insists its multivalent candidate vaccine is "exactly what the government wants," or at least comes "much closer to reaching the goal of developing a multivalent vaccine" than its

competitors. Pl. Supp. Br., 4. Claiming its elimination was unwarranted, GenPhar asserts NIAID unfairly evaluated its proposal so as to constitute arbitrary and capricious agency action. GenPhar points us to two examples.

The first is NIAID's treatment of the adenovirus vector type 5 (Ad5). Recent studies suggested that subjects receiving Ad5 vector vaccines had an increased susceptibility to HIV infection, particularly those volunteers who had higher levels of pre-existing immunity to Ad5 due to prior exposure to the vector. Crucell Tech. Pr., 9. Both GenPhar and Crucell proposed candidate vaccines employing the Ad5 vector in their platform technology, and both suggested different ways to overcome its pre-existing immunity issues. GenPhar now claims NIAID was unduly critical of its approach. Pl. Brief, 21-25.

Relying on early experiments that showed success in overcoming Ad5 immunity issues by increasing vaccine doses, Plaintiff proposed simply to increase the dose of the vaccine vector. Pl.'s Tech. Pr., 38. GenPhar provided no alternate approach and suggested substituting vectors only if an increase in vaccine dose later proved to be ineffective in overcoming Ad5 immunity. *Id.*

The Panel rejected GenPhar's strategy. It found that the early experiments on which GenPhar relied were likely inapplicable to humans. GenPhar's Debriefing, AR 6039. In fact, the Panel found that trials with an Ad5-based HIV vaccine demonstrated not only the vector's ineffectiveness in preventing infection, but a higher susceptibility to infection by individuals with pre-existing immunity. *Id.* Therefore, increasing doses to overcome Ad5 immunity problems would further risk the possibility of adverse reactions. *Id.*

In contrast, Crucell's proposal alternatively offered to avoid using Ad5 entirely. In lieu of Ad5, Crucell suggested the use of back-up adenovirus vectors, including [ ]. Crucell's Tech. Pr., 9. Crucell noted its experience with and intellectual property ownership of [ ] vaccines if NIAID were to select them as back-ups. *Id.*

GenPhar does not dispute the potential hazards associated with the use of Ad5. Rather, Plaintiff seems to take issue with NIAID's disagreement as to the merits of GenPhar's alternate strategy to overcome the immunity issues. Reiterating our limited standard of review, the Court cannot substitute its judgment for that of the agency, and "should intervene only when it is clearly determined that the agency's determinations were irrational or unreasonable." *Baird Corp. v. United States*, 1 Cl. Ct. 662, 664 (1983) (citations omitted). Given the serious safety concerns with Ad5, there is a reasonable justification for the Panel's favoring Crucell's alternate proposal to avoid Ad5 use entirely. We therefore refuse to disturb this highly technical agency decision.

Second, as to GenPhar's other claims of unfair treatment, we again "stay our hand" and defer to the agency's discretion. *See Honeywell, Inc.*, 870 F.2d at 648. In addition to the Ad5 issue, Plaintiff alleges there were at least 15 other occurrences of unfair treatment by NIAID of GenPhar's proposal. Pl. Motion, Ex. 1. For example, NIAID was allegedly unduly critical of GenPhar's lack of experience and reliance on

subcontractors. Plaintiff's proposal identified six subcontractors it intended to use upon contract award, in addition to a project management service to manage those subcontractors. *See e.g.* Pl. Tech. Pr., AR 3794. According to Plaintiff, any criticism of its reliance on subcontracts is unfair because both awardees "have little or no experience in developing the vaccine and certainly have less experience than GenPhar's eight-plus years of experience." Pl.'s Motion, 21.

Nothing in the record supports GenPhar's claims of undue criticism. The Panel critiqued all offerors' relative inexperience. For example, the Panel found it was "not clear that Crucell has solid in-house research capability (basic, pre-clinical and clinical) specific for [a] filovirus vaccine." Panel's Tech. Evaluation Summary, 33. As to Crucell's five years of GMP manufacturing experience, the Panel found it "good, but not extensive." *Id.* Similarly, the Panel criticized IBT as an entity that had been "recently formed, [with] no approved vaccines [or] record of its performance." *Id.* at 10, 14. We cannot conclude NIAID's criticism of GenPhar's proposal was unfair.

The solicitation clearly advised that final selection would be based on the proposals' aggregate technical score, relative cost, and "best overall value" to the government. RFP, 89. To reiterate the applicable law, we apply a heightened deference to the agency's decision when the matter involves a "best value" procurement. *TRW, Inc.*, 98 F.3d at 1327. Not only did GenPhar's proposal rank lowest in technical score, but its total proposed cost was much higher than all three other offerors combined. Plaintiff's evaluated cost was over $155 million higher than IBT's costs, and $170 million higher than that of Crucell. Tech. Evaluation, AR 954. The Panel accordingly found GenPhar's proposed budget "roughly double a reasonable estimate," and concluded "it [did] not appear that there would be a mechanism to reduce the costs to a point where [GenPhar's proposal] would be considered affordable and technically viable." Pl. Tech. Eval. Summary, 83. Given the stark cost and technical differentials, NIAID had a reasonable basis to remove GenPhar from the competition.

We find GenPhar's claims of unfair treatment amount to factual assertions that are uncorroborated by the record or disagreements with NIAID's judgment about highly technical matters. *See E.W. Bliss Co.*, 77 F.3d at 449. Accordingly, we conclude the Panel's technical evaluations and Order of Merit Ranking demonstrate a coherent and reasonable explanation for NIAID's decision to exclude GenPhar from the competition.

C. Challenges to the Procurement Process

In addition to the arguments set forth above, GenPhar claims NIAID violated procurement laws and regulations primarily in two respects. First, NIAID improperly relaxed the solicitation's technical requirements following GenPhar's elimination, especially by moving the trials from the base to the option period, and second, the contract award to Crucell was tainted by an illegal conflict of interest. These actions or omissions allegedly require NIAID to reissue the solicitation and disqualify Crucell from receiving a contract award. We discuss each in turn.

1. Alleged Modifications

There are several reasons to reject the allegation that NIAID improperly modified the solicitation requirements after GenPhar's elimination. First and foremost, GenPhar cannot make a showing of prejudice and therefore lacks standing to challenge the alleged procurement error. As previously noted, we determine prejudice as a threshold matter, prior to reaching the merits of the claim, and consider whether there are sufficient facts in the record that demonstrate GenPhar had greater than an insubstantial chance of winning the contract if the alleged errors were corrected. *See ITAC*, 316 F.3d at 1319; *Am. Fed'n*, 258 F.3d at 1302.

As established above, NIAID had a reasonable basis to exclude GenPhar's technically inferior and high cost proposal from the competition. The Panel had advised that no further action be taken with GenPhar after it determined that no "mechanism" existed to reduce the cost to a point where GenPhar's proposal would be considered "affordable and technically viable." Pl. Tech. Eval. Summary, 83. Because the allegedly illegal modifications occurred after GenPhar's proper elimination from the competition, GenPhar cannot show it would have had greater than an insubstantial chance of receiving the contract absent the alleged errors. Without any chance, much less a substantial one, to win the award, GenPhar lacks standing to proceed with this claim.

Even if we were to assume standing exists, nothing in the record supports the conclusion that an improper relaxing of technical requirements occurred. The solicitation indicated that negotiations might involve modifications of "milestones, progress, schedule, budget, or product . . ." consistent with the agency's needs. BAA, Att. 6, Sec. 3. At oral argument, Plaintiff admitted that none of these tasks were changed, and that it only took issue with NIAID's movement of those items from the base to the options period. Tr. at 23. Because the alleged changes call for essentially the same performance and were authorized, we find no material departure by the agency from the scope of the original procurement.

2. Alleged Conflict of Interest

Finally, Plaintiff asserts Crucell's award was tainted by a conflict of interest with NIAID. According to GenPhar, Crucell's ongoing collaborative research with VRC, a division of NIAID, resulted in NIAID having its own "horse in the race." Pl. Supp. Br., 9; Tr. at 52. Again, this claim is uncorroborated in the record.

To simply allege the agency treated offerors unequally due to a pre-existing business arrangement with one of the awardees is insufficient evidence of a "clear and prejudicial" violation. *See Impresa*, 238 F.3d at 1333. Under the FAR, a conflict of interest arises when, "because of other activities or relationships with other persons, a person is unable or potentially unable to render impartial assistance or advice to the government, or the person's objectivity in performing the contract work is or might be otherwise impaired, or a person has an unfair competitive advantage." 48 C.F.R.

§ 2.101. GenPhar bears the burden of identifying "hard facts" to establish such a violation. *See CACI, Inc.*, 719 F.2d at 1582; *see also Galen Med. Assoc., Inc. v. United States*, 369 F.3d 1324, 1335 (Fed. Cir. 2004) (citations omitted).

Nothing in the record suggests an actual or apparent conflict between NIAID and Crucell, though GenPhar insists a conflict is inherent by virtue of the CRADA. A standard CRADA would require Crucell to pay NIAID royalties, milestone payments and percentage income for work using developments from the collaboration. Pl. Motion, 27. Crucell would also pay licensing fees to NIAID derived from its exclusive patent license to practice the Ebola vaccine. *Id.* Consequently, Plaintiff alleges a financial interest adverse to NIAID's obligations to award a contract promoting the "best overall value" to the government. *Id.*

We find this claim speculative at best. The mere existence of a prior business relationship is insufficient for GenPhar to establish the agency's violation of statutory or regulatory conflict of interest provisions. No evidence exists that the proposal was structured to favor Crucell over its competitors. Nor is there any allegation that Crucell was involved in establishing the specifications for this solicitation. Plaintiff's allegation that NIAID stands to gain financially from an award to Crucell as a result of the CRADA is merely "suspicion and innuendo." *See CACI, Inc.*, 719 F.2d at 1582. Without hard facts, the mere allegation is insufficient to support the claim. *See id.*

In conclusion, we reject GenPhar's claims that NIAID changed the solicitation's requirements and ignored an illegal conflict of interest. GenPhar has failed in the first instance to demonstrate prejudice. Irrespective of this deficiency, GenPhar's technical inferiority and high cost would still preclude a "best value" award in accordance with the terms of the solicitation.

III. CONCLUSION

For the foregoing reasons, the Defendant's and Intervenors' respective Motions for Judgment on the Administrative Record are GRANTED. Plaintiff's Motion for Judgment on the Administrative Record is DENIED. The Clerk is directed to DISMISS the Complaint. No costs.

IT IS SO ORDERED.

s/ Lawrence M. Baskir
LAWRENCE M. BASKIR
Judge